

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

NORTHFIELD LABORATORIES INC /DE/  
Form 10-Q  
January 14, 2003

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE  
ACT OF 1934

FOR THE PERIOD ENDED NOVEMBER 30, 2002

OR

TRANSITION REPORT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF  
1934

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 0-24050

NORTHFIELD LABORATORIES INC.  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction  
of incorporation or organization)

36-3378733  
(I.R.S. Employer  
Identification Number)

1560 SHERMAN AVENUE, SUITE 1000, EVANSTON, ILLINOIS  
(Address of principal executive offices)

60201-4800  
(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (847) 864-3500

FORMER NAME, FORMER ADDRESS AND FORMER FISCAL YEAR, IF CHANGED SINCE LAST  
REPORT: NOT APPLICABLE

INDICATE BY CHECK MARK WHETHER THE REGISTRANT (1) HAS FILED ALL REPORTS  
REQUIRED TO BE FILED BY SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF  
1934 DURING THE PRECEDING 12 MONTHS (OR FOR SUCH SHORTER PERIOD THAT THE  
REGISTRANT WAS REQUIRED TO FILE SUCH REPORTS), AND (2) HAS BEEN SUBJECT TO SUCH  
FILING REQUIREMENTS FOR THE PAST 90 DAYS.

YES X NO  
--- ---

APPLICABLE ONLY TO ISSUER INVOLVED IN BANKRUPTCY  
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

INDICATE BY CHECK MARK WHETHER THE REGISTRANT HAS FILED ALL DOCUMENTS AND  
REPORTS REQUIRED TO BE FILED BY SECTION 12, 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934 SUBSEQUENT TO THE DISTRIBUTION OF SECURITIES UNDER A PLAN  
CONFIRMED BY A COURT. YES NO  
--- ---

AS OF NOVEMBER 30, 2002, REGISTRANT HAD 14,265,875 SHARES OF COMMON STOCK  
OUTSTANDING

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This Quarterly Report contains forward-looking statements concerning, among other things, our prospects, clinical and regulatory developments affecting our potential product and our business strategies. These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should," "believes" and similar terms.

These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events, including those discussed under "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. Because these forward-looking statements involve risks and uncertainties, actual results may differ significantly from those predicted in these forward-looking statements. You should not place a lot of weight on these statements. These statements speak only as of the date of this document or, in the case of any document incorporated by reference, the date of that document.

All subsequent written and oral forward-looking statements attributable to Northfield or any person acting on our behalf are qualified by the cautionary statements in this section and in our Annual Report. We will have no obligation to revise these forward-looking statements.

### INDEPENDENT ACCOUNTANTS' REVIEW REPORT

The Board of Directors  
Northfield Laboratories Inc.:

We have reviewed the balance sheet of Northfield Laboratories Inc. (a company in the development stage) as of November 30, 2002, and the related statements of operations for the three-month periods ended November 30, 2002 and 2001, and statements of operations and cash flows for the six-month periods ended November 30, 2002 and 2001, and for the period from June 19, 1985 (inception) through November 30, 2002. We have also reviewed the statements of shareholders' equity (deficit) for the six-month period ended November 30, 2002 and for the period from June 19, 1985 (inception) through November 30, 2002. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards generally accepted in the United States of America, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the financial statements referred to above for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with auditing standards generally accepted in the United States of America, the balance sheet of Northfield Laboratories Inc. as of May 31, 2002, and the related statements of operations, shareholders' equity (deficit), and cash flows for the year then ended and for the period from June 19, 1985 (inception) through May 31, 2002 (not presented herein); and in our report dated July 16, 2002, we expressed an unqualified

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

opinion on those financial statements. In our opinion, the information set forth in the accompanying balance sheet as of May 31, 2002 and in the accompanying statement of shareholders' equity (deficit) is fairly stated, in all material respects, in relation to the statements from which they have been derived.

/s/ KPMG LLP

Chicago, Illinois  
December 16, 2002

NORTHFIELD LABORATORIES INC.  
(a company in the development stage)

### Balance Sheets

November 30, 2002 (unaudited) and May 31, 2002

	ASSETS	NOVEMBER 30 2002
		-----
Current assets:		
Cash		\$ 9,374,09
Marketable securities		2,689,12
Prepaid expenses		439,50
Other current assets		11,38
		-----
Total current assets		12,514,10
Property, plant, and equipment, net		1,956,86
Other assets		71,90
		-----
		\$ 14,542,87
		=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable		\$ 324,41
Accrued expenses		320,00
Accrued compensation and benefits		316,80
		-----
Total current liabilities		961,22
Other liabilities		172,78
		-----
Total liabilities		1,134,00
		-----
Shareholders' equity:		
Preferred stock, \$.01 par value. Authorized 5,000,000 shares; none issued and outstanding		-

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Common stock, \$.01 par value. Authorized 30,000,000 shares;  
issued and outstanding 14,265,875 at November 30, 2002  
and May 31, 2002.

Additional paid-in capital 142,65  
Deficit accumulated during the development stage 117,503,27  
(104,237,06

Total shareholders' equity 13,408,86

\$ 14,542,87  
=====

See accompanying notes to financial statements.

NORTHFIELD LABORATORIES INC.  
(a company in the development stage)

Statements of Operations

Three and six month periods ended November 30, 2002 and 2001 and for the period  
from June 19, 1985 (inception) through November 30, 2002

	THREE MONTHS ENDED NOVEMBER 30,		SIX MONTHS ENDED NOVEMBER 30,
	2002 (UNAUDITED)	2001 (UNAUDITED)	2002 (UNAUDITED)
Revenues - license income	\$ --	--	--
Costs and expenses:			
Research and development	2,243,311	1,910,675	4,269,113
General and administrative	960,746	524,809	1,889,903
	3,204,057	2,435,484	6,159,016
Other income and expense:			
Interest income	60,196	269,780	137,566
Interest expense	--	--	--
	60,196	269,780	137,566
Net loss	\$ (3,143,861)	(2,165,704)	(6,021,450)
Net loss per share - basic and diluted	\$ (0.22)	(0.15)	(0.42)

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Shares used in calculation of			
per share data - basic and diluted	14,265,875	14,265,875	14,265,875
	=====	=====	=====

See accompanying notes to financial statements.

NORTHFIELD LABORATORIES INC.  
(a company in the development stage)

Statements of Shareholders' Equity (Deficit)

Six month period ended November 30, 2002 (unaudited) and for the period  
from June 19, 1985 (inception) through November 30, 2002

	NUMBER OF SHARES	AGGREG AMOU
	-----	-----
Issuance of common stock on August 27, 1985	--	\$ --
Issuance of Series A convertible preferred stock at \$4.00 per share on August 27, 1985 (net of costs of issuance of \$79,150)	--	--
Net loss	--	--
	-----	-----
Balance at May 31, 1986	--	--
Net loss	--	--
Deferred compensation relating to grant of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1987	--	--
Issuance of Series B convertible preferred stock at \$35.68 per share on August 14, 1987 (net of costs of issuance of \$75,450)	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1988	--	--
Issuance of common stock at \$24.21 per share on June 7, 1988 (net of costs of issuance of \$246,000)	--	--
Conversion of Series A convertible preferred stock to common stock on June 7, 1988	--	--
Conversion of Series B convertible preferred stock to common stock on June 7, 1988	--	--
Exercise of stock options at \$2.00 per share	--	--
Issuance of common stock at \$28.49 per share on March 6, 1989 (net of costs of issuance of \$21,395)	--	--
Issuance of common stock at \$28.49 per share on March 30, 1989 (net of costs of issuance of \$10,697)	--	--
Sale of options at \$28.29 per share to purchase common stock at \$.20 per share on March 30, 1989 (net of costs of issuance of \$4,162)	--	--
Net loss	--	--
Deferred compensation relating to grant of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Balance at May 31, 1989	--	--
Net loss	--	--
Deferred compensation relating to grant of stock options	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1990	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1991	--	--
Exercise of stock warrants at \$5.60 per share	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1992	--	--
Exercise of stock warrants at \$7.14 per share	--	--
Issuance of common stock at \$15.19 per share on April 19, 1993 (net of costs of issuance of \$20,724)	--	--
Net loss	--	--
Amortization of deferred compensation	--	--
	-----	-----
Balance at May 31, 1993	--	\$ --
	-----	-----

SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE
NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES	AGGREGATE AMOUNT		
--	\$ --	--	\$ --	\$ (28,000)	\$ --
250,000	250,000	--	--	670,850	--
--	--	--	--	--	(607,688)
250,000	250,000	--	--	642,850	(607,688)
--	--	--	--	--	(2,429,953)
--	--	--	--	2,340,000	--
--	--	--	--	--	--
250,000	250,000	--	--	2,982,850	(3,037,641)
--	--	200,633	200,633	6,882,502	--
--	--	--	--	--	(3,057,254)
--	--	--	--	--	--

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

250,000	250,000	200,633	200,633	9,865,352	(6,094,895)
--	--	--	--	9,749,870	--
(250,000)	(250,000)	--	--	237,500	--
--	--	(200,633)	(200,633)	190,601	--
--	--	--	--	93,759	--
--	--	--	--	4,976,855	--
--	--	--	--	2,488,356	--
--	--	--	--	7,443,118	--
--	--	--	--	--	(791,206)
--	--	--	--	683,040	--
--	--	--	--	--	--
--	--	--	--	35,728,451	(6,886,101)
--	--	--	--	--	(3,490,394)
--	--	--	--	699,163	--
--	--	--	--	--	--
--	--	--	--	36,427,614	(10,376,495)
--	--	--	--	--	(5,579,872)
--	--	--	--	--	--
--	--	--	--	36,427,614	(15,956,367)
--	--	--	--	503,100	--
--	--	--	--	--	(7,006,495)
--	--	--	--	--	--
--	--	--	--	36,930,714	(22,962,862)
--	--	--	--	106,890	--
--	--	--	--	5,663,710	--
--	--	--	--	--	(8,066,609)
--	--	--	--	--	--
--	\$ --	--	\$ --	\$42,701,314	\$ (31,029,471)

NORTHFIELD LABORATORIES INC.  
(a company in the development stage)

Statements of Shareholders' Equity (Deficit)

Six month period ended November 30, 2002 (unaudited) and for the period  
from June 19, 1985 (inception) through November 30, 2002

PREFERRED STOCK

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

	NUMBER OF SHARES	AGGREG AMOU
Net loss	--	\$ --
Issuance of common stock at \$6.50 per share on May 26, 1994 (net of costs of issuance of \$2,061,149)	--	--
Cancellation of stock options	--	--
Amortization of deferred compensation	--	--
Balance at May 31, 1994	--	--
Net loss	--	--
Issuance of common stock at \$6.50 per share on June 20, 1994 (net of issuance costs of \$172,500)	--	--
Exercise of stock options at \$7.14 per share	--	--
Exercise of stock options at \$2.00 per share	--	--
Cancellation of stock options	--	--
Amortization of deferred compensation	--	--
Balance at May 31, 1995	--	--
Net loss	--	--
Issuance of common stock at \$17.75 per share on August 9, 1995 (net of issuance costs of \$3,565,125)	--	--
Issuance of common stock at \$17.75 per share on September 11, 1995 (net of issuance costs of \$423,238)	--	--
Exercise of stock options at \$2.00 per share	--	--
Exercise of stock options at \$6.38 per share	--	--
Exercise of stock options at \$7.14 per share	--	--
Cancellation of stock options	--	--
Amortization of deferred compensation	--	--
Balance at May 31, 1996	--	--
Net loss	--	--
Exercise of stock options at \$0.20 per share	--	--
Exercise of stock options at \$2.00 per share	--	--
Exercise of stock options at \$7.14 per share	--	--
Amortization of deferred compensation	--	--
Balance at May 31, 1997	--	--
Net loss	--	--
Exercise of stock options at \$7.14 per share	--	--
Amortization of deferred compensation	--	--
Balance at May 31, 1998	--	--
Net loss	--	--
Non-cash compensation	--	--
Exercise of stock options at \$7.14 per share	--	--
Exercise of stock warrants at \$8.00 per share	--	--
Balance at May 31, 1999	--	--
Net loss	--	--
Non-cash compensation	--	--
Exercise of stock options at \$13.38 per share	--	--



Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

Balance at May 31, 2000	--	--
Net loss	--	--
Non-cash compensation	--	--
Exercise of stock options at \$6.38 per share	--	--
Exercise of stock options at \$10.81 per share	--	--
	-----	-----
Balance at May 31, 2001	--	--
Net loss	--	--
	-----	-----
Balance at May 31, 2002	--	--
Net loss	--	--
	-----	-----
Balance at November 30, 2002	--	\$ --
	=====	=====

SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE
NUMBER OF SHARES	AGGREGATE AMOUNT	NUMBER OF SHARES	AGGREGATE AMOUNT		
-----	-----	-----	-----	-----	-----
--	\$ --	--	\$ --	\$ --	\$ (7,363,810)
--	--	--	--	14,163,851	--
--	--	--	--	(85,400)	--
--	--	--	--	--	--
	-----		-----	-----	-----
--	--	--	--	56,779,765	(38,393,281)
--	--	--	--	--	(7,439,013)
--	--	--	--	2,261,250	--
--	--	--	--	71,300	--
--	--	--	--	373,264	--
--	--	--	--	(106,750)	--
--	--	--	--	--	--
	-----		-----	-----	-----
--	--	--	--	59,378,829	(45,832,294)
--	--	--	--	--	(4,778,875)
--	--	--	--	48,324,374	--
--	--	--	--	7,360,187	--
--	--	--	--	362,937	--
--	--	--	--	9,555	--
--	--	--	--	71,300	--
--	--	--	--	(80,062)	--
--	--	--	--	--	--
	-----		-----	-----	-----
--	--	--	--	115,427,120	(50,611,169)
--	--	--	--	--	(4,245,693)

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

--	--	--	--	50,025	--
--	--	--	--	463,540	--
--	--	--	--	71,300	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	116,011,985	(54,856,862)
--	--	--	--	--	(5,883,378)
--	--	--	--	35,650	--
--	--	--	--	--	--
-----	-----	-----	-----	-----	-----
--	--	--	--	116,047,635	(60,740,240)
--	--	--	--	--	(7,416,333)
--	--	--	--	14,354	--
--	--	--	--	124,775	--
--	--	--	--	998,750	--
-----	-----	-----	-----	-----	-----
--	--	--	--	117,185,514	(68,156,573)
--	--	--	--	--	(9,167,070)
--	--	--	--	57,112	--
--	--	--	--	33,425	--
-----	-----	-----	-----	-----	-----
--	--	--	--	117,276,051	(77,323,643)
--	--	--	--	--	(10,174,609)
--	--	--	--	--	--
--	--	--	--	38,220	--
--	--	--	--	189,000	--
-----	-----	-----	-----	-----	-----
--	--	--	--	117,503,271	(87,498,252)
--	--	--	--	--	(10,717,360)
-----	-----	-----	-----	-----	-----
--	--	--	--	117,503,271	(98,215,612)
-----	-----	-----	-----	-----	-----
--	--	--	--	--	(6,021,450)
-----	-----	-----	-----	-----	-----
--	\$	--	\$	\$117,503,271	\$(104,237,062)
=====	=====	=====	=====	=====	=====

NORTHFIELD LABORATORIES INC.  
(a company in the development stage)

Statements of Cash Flows

Six month periods ended November 30, 2002 and 2001  
and the cumulative period from June 19, 1985  
(inception) through November 30, 2002

SIX MONTHS ENDED NOVEM

-----  
2002

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

	-----
	(unaudited)
Cash flows from operating activities:	
Net loss	\$ (6,021,450)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	406,623
Non-cash compensation	--
Loss on sale of equipment	--
Changes in assets and liabilities:	
Prepaid expenses	100,502
Other current assets	(9,950)
Other assets	--
Accounts payable	(753,293)
Accrued expenses	109,892
Accrued compensation and benefits	(22,045)
Other liabilities	(4,969)
	-----
Net cash used in operating activities	(6,194,690)
	-----
Cash flows from investing activities:	
Purchase of property, plant, equipment, and capitalized engineering costs	(146,766)
Proceeds from sale of land and equipment	--
Proceeds from matured marketable securities	--
Proceeds from sale of marketable securities	--
Purchase of marketable securities	(1,953,138)
	-----
Net cash provided by (used in) investing activities	(2,099,904)
	-----
Cash flows from financing activities:	
Proceeds from issuance of common stock	--
Payment of common stock issuance costs	--
Proceeds from issuance of preferred stock	--
Proceeds from sale of stock options to purchase common shares	--
Proceeds from issuance of notes payable	--
Repayment of notes payable	--
	-----
Net cash provided by financing activities	--
	-----
Net (decrease) increase in cash	(8,294,594)
Cash at beginning of period	17,668,687
	-----
Cash at end of period	\$ 9,374,093
	=====

See accompanying notes to financial statements.

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

NORTHFIELD LABORATORIES INC.  
(a company in the development stage)

Notes to Financial Statements

November 30, 2002

(1) BASIS OF PRESENTATION

The interim financial statements presented are unaudited but, in the opinion of management, have been prepared in conformity with accounting principles generally accepted in the United States of America applied on a basis consistent with those of the annual financial statements. Such interim financial statements reflect all adjustments (consisting of normal recurring accruals) necessary for a fair presentation of the financial position and the results of operations for the interim periods presented. The results of operations for the interim period presented are not necessarily indicative of the results to be expected for the year ending May 31, 2003. The interim financial statements should be read in connection with the audited financial statements for the year ended May 31, 2002.

(2) COMPUTATION OF NET LOSS PER SHARE

Basic earnings per share is based on the weighted average number of shares outstanding and excludes the dilutive effect of unexercised common stock equivalents. Diluted earnings per share is based on the weighted average number of shares outstanding and includes the dilutive effect of unexercised common stock equivalents. Because the Company reported a net loss for all periods presented, basic and diluted per share amounts are the same.

(3) LIQUIDITY

The Company has incurred recurring losses since its inception and expects that significant additional expenditures will be required to successfully commercialize PolyHeme. The Company has financed its research and development and other activities to date primarily through the public and private sale of equity securities and, to a more limited extent, through the licensing of product rights. As of November 30, 2002, the Company had cash and marketable securities totaling \$12,063,000. The Company is actively pursuing additional financing to fund its continued operations. The Company may also enter into collaborative arrangements with strategic partners, which could provide the Company with additional funding or absorb expenses the Company would otherwise be required to pay. Any one or a combination of these sources may be utilized to raise the required funding. Business or market conditions may not be favorable, which could delay or prevent the Company from raising additional capital or entering into a collaborative arrangement. If the Company is unable to obtain additional capital or enter into a collaborative arrangement, the Company may be required to curtail its product development and other activities and substantially reduce its scope of operations.

ITEM 2.  
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Since Northfield's incorporation in 1985, we have devoted substantially

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

all of our efforts and resources to the research, development and clinical testing of our potential product, PolyHeme™. We have incurred operating losses during each year of our operations since inception and expect to incur substantial additional operating losses for the next several years. From Northfield's inception through November 30, 2002, we have incurred operating losses totaling \$104,237,000.

### RECENT EVENTS

In August 2001, we submitted a Biologics License Application to the Food and Drug Administration seeking regulatory approval for the commercial manufacture and sale of PolyHeme. In November 2001, the FDA issued a refusal to file letter with respect to our Biologics License Application. Since that time, we have had numerous meetings and follow-up discussions with the FDA, have responded to the FDA's questions and are attempting to reach a consensus with the FDA in order to move forward as quickly as possible toward regulatory approval for PolyHeme.

Based on our dialogue with the FDA, we submitted a proposed protocol to the FDA in October 2002 for an additional clinical trial in which PolyHeme would be used for the first time in civilian trauma applications to treat severely injured patients before they reach a hospital. Under our proposed protocol, treatment with PolyHeme would begin at the scene of the injury and continue during transport to the hospital by either ground or air ambulance. Because of the complex ethical and legal issues associated with obtaining a waiver of informed consent as part of our proposed trial protocol, we announced that we anticipated that the FDA would require

more than the traditional 30-day review period to complete its evaluation of our proposal.

In November 2002, the FDA responded with questions and comments regarding our protocol proposal. The FDA's response continued to encourage the concept of a civilian trauma study in the urban prehospital setting, including the proposed primary endpoint of increased survival. The response included questions and comments related to many of the administrative aspects of conducting such a trial in order to be certain that all requirements of the specific regulation allowing for a waiver of consent are fully satisfied. In particular, there were comments regarding the role of both the hospital Institutional Review Board and the local community in authorizing such a study. There were additional comments related to the collection and monitoring of clinical data to ensure maximum safety of the enrolled patients.

We also submitted a request for special protocol assessment for our proposed civilian trauma trial. A special protocol assessment represents an acknowledgement and confirmation of a mutual agreement between the sponsoring company and the FDA that successful completion of the proposed trial will form the basis for product approval. If agreement is reached, the FDA reduces the agreement to writing and makes it part of the administrative record. We also intend to request that PolyHeme be designated as a fast track product. It may then be possible for certain portions of our Biologics License Application to be accepted for review prior to completion of our proposed clinical trial, a so-called "rolling BLA." In parallel with our proposed civilian trauma trial, we are also currently developing a treatment Investigational New Drug application with the U.S. Army. The FDA regulatory

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

process is subject to significant risks and uncertainties. The nature, timing and costs of the efforts necessary for us to obtain regulatory approval for PolyHeme, and the timing of any future revenues from the commercial sale of PolyHeme, cannot therefore be reasonably estimated at this time because of the current regulatory status of PolyHeme and the wide range of possible outcomes arising from our discussions with the FDA.

Our success will depend on several factors, including our ability to obtain FDA regulatory approval of PolyHeme and our manufacturing facilities, obtain sufficient quantities of blood to manufacture PolyHeme in commercial quantities, manufacture and distribute PolyHeme in a cost-effective manner, enforce our patent positions and raise sufficient capital to fund these activities. We have experienced significant delays in the development and clinical testing of PolyHeme. We cannot ensure that we will be able to achieve these goals or that we will be able to realize product revenues or profitability on a sustained basis or at all.

We anticipate that research and development expenses will increase during the foreseeable future. These expected increases are attributable to additional clinical trials, monitoring and reporting the results of these trials and continuing process development associated with improving our manufacturing capacity to permit commercial-scale production of PolyHeme. We expect that general and administrative expenses will increase over the foreseeable future as a result of increased costs relating to the expansion of our organization in support of anticipated commercial operations.

### RESULTS OF OPERATIONS

We reported no revenues for either of the three-month periods or six-month periods ended November 30, 2002 or 2001. From Northfield's inception through November 30, 2002, we have reported total revenues of \$3,000,000, all of which were derived from licensing fees.

### OPERATING EXPENSES

Operating expenses for our second fiscal quarter ended November 30, 2002 totaled \$3,204,000, an increase of \$769,000 from the \$2,435,000 reported in the second quarter of the fiscal 2002. Measured on a percentage basis, operating expenses in the second quarter of fiscal 2003 increased by 31.6%. The difference was due to higher costs for manufacturing supplies and higher costs for professional services and associated costs incurred in connection with the defense of a proxy contest relating to our 2002 annual meeting of shareholders.

Operating expenses for the six-month period ended November 30, 2002 totaled \$6,159,000, an increase of \$232,000, or 3.9%, from the \$5,927,000 reported for the six-month period ended November 30, 2001. The increase was due to higher costs associated with the defense of our contested proxy.

Research and development expenses for the second quarter of fiscal 2003 totaled \$2,243,000, an increase of \$332,000, or 17.4%, from the \$1,911,000 reported in the second quarter of fiscal 2002. Higher expenses were recognized during the second quarter of fiscal 2003 than in the second quarter of fiscal 2002 related to ongoing process enhancements to filters and packaging. The fiscal 2003 second quarter expenses include evaluation purchases to assess new technologies as well as production materials and some modest advance purchasing to

mitigate anticipated price increases.

Research and development expenses for the six-month period ended November 30, 2002 totaled \$4,269,000, a decrease of \$290,000, or 6.4%, from the \$4,559,000 reported in the comparable prior year period. Increases relating to the purchase of manufacturing supplies were offset by larger decreases in compensation and clinical trials related expenses from those incurred in the prior year period.

We anticipate that research and development expenses will increase significantly in the third and fourth quarter of fiscal 2003. Additional costs are being planned for multi-center clinical trials in support of expanded product indications, third party clinical monitoring, biostatistical analysis, report preparation and continued expansion of our manufacturing organization. Northfield is conducting a national search for a medical director to directly oversee the planned clinical trials.

General and administrative expenses in the second quarter of fiscal 2003 totaled \$961,000 compared to expenses of \$525,000 in the second quarter of 2002, representing an increase of \$436,000, or 83.0%. This increase was due to increased professional service fees related to the proxy contest in connection with our annual meeting and the increased cost of directors and officers insurance, increased public relations costs and executive recruiting costs.

General and administrative expenses for the six-month period ended November 30, 2002 totaled \$1,890,000, representing an increase of \$522,000, or 38.2%, from general and administrative expenses of \$1,368,000 incurred during the six-month period ended November 30, 2001. Virtually, all of the \$522,000 variance is attributable to expenses incurred related to the proxy contest in connection with our annual meeting. Other expenses incurred compared to the same prior year period showed a reduction in compensation costs offsetting increased expenses for directors and officers insurance, public relations and recruiting.

With the exception of enhancing the Company's investor relation capabilities, Northfield is not planning any new general and administrative programs over the balance of the fiscal year. Securing regulatory approval for PolyHeme is the highest priority item. Once there is greater clarity on the probability and timing of approval, general and administrative expenses are expected to increase to support the commercialization of our product.

#### INTEREST INCOME

Interest income in the second quarter of fiscal 2003 totaled \$60,000, or a \$210,000 decrease from the \$270,000 in interest income reported in the second quarter of fiscal 2002. Short term available interest rates declined in excess of 400 basis points from the second quarter of fiscal

2002, which along with lower available investment balances accounted for the decrease in interest income. In the absence of a major cash infusion, interest income will continue to be significantly below prior year levels.

For the six-month period ended November 30, 2002, interest income totaled \$138,000, or a \$433,000 decrease in interest income from the six-month period ended November 30, 2001. Lower investment balances and lower interest rates combined to cause the decrease.

#### NET LOSS

The net loss for the second quarter ended November 30, 2002 was \$3,144,000, or \$.22 per basic share, compared to a net loss of \$2,166,000, or \$.15 per basic share, for the second quarter ended November 30, 2001. The increase in the loss per basic share is primarily the result of costs relating to increased purchases of manufacturing supplies, expenses related to the proxy contest in connection with our annual meeting and lower interest income.

The six-month net loss for the period ended November 30, 2002 totaled \$6,021,000, or \$.42 per basic share, compared to a net loss of \$5,356,000, or \$.38 per basic share for the six-month period ended November 30, 2001 and is the result of the expenses related to the proxy contest

in connection with our annual meeting and lower interest income.

#### LIQUIDITY AND CAPITAL RESOURCES

From Northfield's inception through November 30, 2002, we have used cash for operating activities and for the purchase of property, plant, equipment and engineering services in the amount of \$103,940,000. For the six-month periods ended November 30, 2002 and 2001, these cash expenditures totaled \$6,341,000 and \$5,713,000, respectively. The increased cash outlay for the first half of fiscal 2003 compared to the comparable prior year period resulted from a higher net loss.

We have incurred recurring losses since our inception and expect that significant additional expenditures will be required to successfully commercialize PolyHeme. We have financed our research and development and other activities to date primarily through the public and private sale of equity securities and, to a more limited extent, through the licensing of product rights. As of November 30, 2002, we had cash and marketable securities totaling \$12,063,000.

We believe our existing capital resources will be adequate to satisfy our current operating requirements and maintain our existing pilot manufacturing plant and office facilities for approximately the next 12 months. We will require substantial additional capital to continue our operations beyond the next 12 months and to conduct our planned additional clinical trials.

Northfield is actively pursuing additional financing to fund our



## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

continued operations,

including the proposed additional clinical trials described above. We may issue additional equity or debt securities to the public or in private placement transactions. We may also enter into collaborative arrangements with strategic partners, which could provide us with additional funding or absorb expenses we would otherwise be required to pay. Any one or a combination of these sources may be utilized to raise the required funding. Business or market conditions may not be favorable, which could delay or prevent us from raising additional capital or entering into a collaborative arrangement. If we are unable to obtain additional capital or enter into a collaborative arrangement, we may be required to curtail our product development and other activities and substantially reduce our scope of operations.

As of May 31, 2002, we had net operating loss carryforwards of approximately \$98,000,000 to offset future federal taxable income through 2022. Due to the degree of uncertainty related to the ultimate realization of such prior losses, no benefit has been recognized in our financial statements as of November 30, 2002.

We are currently unable to fund the construction of a large-scale greenfield manufacturing facility, which is estimated to cost approximately \$70 million, without raising substantial additional capital. Currently, we have manufacturing capacity of approximately 10,000 units. Initial engineering on the leased space adjacent to our existing manufacturing facility is completed. This engineering indicates an additional capacity of 75,000 units could be developed in approximately 16 to 20 months at a cost of approximately \$30 million. Like a large-scale greenfield manufacturing facility, significant additional funding will be required before the smaller scale expansion facility could be completed. Northfield has not yet committed to the build-out. We view the smaller facility as

financially prudent yet large enough for commercial viability.

Our capital requirements may vary materially from those now anticipated because of the results of our clinical testing of PolyHeme, the establishment of relationships with strategic partners, changes in the scale, timing or cost of our commercial manufacturing facility, competitive and technological advances, the FDA regulatory process, changes in our marketing and distribution strategy and other factors.

### CRITICAL ACCOUNTING POLICIES

The preparation of financial statements requires management to make estimates and assumptions that affect amounts reported therein. The Company believes the following critical accounting policy affects its more significant judgments and estimates used in the preparation of its consolidated financial statements.

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

### NET DEFERRED TAX ASSETS VALUATION

The Company records its net deferred tax assets in the amount that it expects to realize based on projected future taxable income. In assessing the appropriateness of its valuation, assumptions and estimates are required such as the Company's ability to generate future taxable income. In the event that the Company were to determine that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. As of November 30, 2002, the Company has recorded a 100 percent valuation allowance against its deferred tax asset.

### CONTRACTUAL OBLIGATIONS

The following table reflects a summary of the Company's contractual cash obligations as of November 30, 2002:

Contractual Cash Obligations	Total	Less Than One Year	1-3 Years	4
Lease Obligations(1)	\$2,001,072	851,462	1,076,154	
Other Obligations(2)	1,849,364	886,775	962,589	
Total Contractual Cash Obligations	\$3,850,436	1,738,237	2,038,743	

(1) Northfield's Evanston lease agreement is cancellable with six months notice combined with a termination payment equal to six months base rent and six months of additional rental payments. If the lease were terminated today the termination payment would be \$315,530.

(2) Other obligations are comprised of employment agreements for Steven A. Gould, M.D., Jack Kogut, combined with a consulting agreement.

### RECENT ACCOUNTING PRONOUNCEMENTS

In August 2001, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 143, Accounting for Asset Retirement Obligations, which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and for the associated asset retirement costs. FASB Statement No. 143 requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of tangible long-lived assets that result from the acquisition, construction, development and/or normal use of the assets. The enterprise also is to record a corresponding increase to the carrying amount of the related long-lived asset (i.e., the associated asset retirement costs) and to depreciate that cost over the life of the asset. The liability is changed at the end of each period to reflect the passage of time and changes in the estimated future cash flows underlying the initial fair value measurement. Adoption of FASB Statement No. 143 is required for fiscal years beginning after June 15, 2002. Upon adoption of this provision we expect to record an additional liability and corresponding asset of approximately \$138,000 to reflect the restoration costs for the leased facility that houses our current manufacturing operations.

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

The marketable security investments of the Company have been made for investment (as opposed to trading) purposes. Interest rate risk with respect to the investments of the Company is not significant as all such investments are in U.S. dollar cash equivalents and short-term investments (with maturities of less than 12 months), which are by their nature less sensitive to interest rate movements. The investments of the Company are generally made in U.S. government and federal agency bonds, high-grade commercial paper, corporate bonds and certificates of deposit. A one percentage point decrease or increase on an investment balance of \$12.1 million would change annual interest income by \$121,000.

### ITEM 4. CONTROLS AND PROCEDURES

The Company maintains a set of disclosure controls and procedures and internal controls designed to ensure that information required to be disclosed in the Company's filings under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. The Company's principal executive and financial officers have evaluated its disclosure controls and procedures within 90 days prior to the filing of this Quarterly Report on Form 10-Q and have determined that such disclosure controls and procedures are effective.

Subsequent to the Company's evaluation, there were no significant changes in internal controls or other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

## PART II. OTHER INFORMATION

### Item 6. Exhibits

- a) Exhibit 10.17 - Form of Severance Protection Agreement between Northfield Laboratories Inc. and each of the following officers:  
Marc Doubleday - Vice President Process Engineering  
Robert McGinnis - Vice President Manufacturing Development  
Sophia Twaddell - Vice President Corporate Communications

Exhibit 15 - Acknowledgment of Independent Certified Public Accountants

Exhibit 99.1 - Certification of Chief Executive Officer

Exhibit 99.2 - Certification of Chief Financial Officer

- b) Report on Form 8-K:

The Company filed a report dated August 9, 2002, in which Steven A. Gould, M.D., Chief Executive Officer and Jack J. Kogut, Chief Financial Officer of Northfield Laboratories Inc., submitted certifications to the Securities and Exchange Commission pursuant to Section 906 of the Sarbanes-Oxley Act.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company in the capacities indicated on January 14, 2003.

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

SIGNATURE	TITLE
/s/ STEVEN A. GOULD, M.D. ----- Steven A. Gould, M.D.	Chairman of the Board and Chief Executive Officer (principal executive officer)
/s/ JACK J. KOGUT ----- Jack J. Kogut	Vice President - Finance, Secretary and Treasurer (principal financial and accounting officer)

CERTIFICATION

I, Steven A. Gould, M.D., Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Northfield Laboratories Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

## Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

- b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: January 14, 2003

/s/ Steven A. Gould, M.D.

-----  
Steven A. Gould, M.D.  
Chief Executive Officer

### CERTIFICATION

I, Jack J. Kogut, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Northfield Laboratories Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to

Edgar Filing: NORTHFIELD LABORATORIES INC /DE/ - Form 10-Q

record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

- b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: January 14, 2003

/s/ Jack J. Kogut

-----

Jack J. Kogut  
Chief Financial Officer